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Applicants:	Jennifer L. West and Brenda K. Manning		
Serial No.:	09/935,168	Art Unit:	1644
Filed:	August 21, 2001	Examiner:	Phuong N. Huynh
For:	*TISSUE ENGINEERING SCAFFOLDS PROMOTING MATRIX PROTEIN PRODUCTION*		

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT

Sir:

Pursuant to 37 C.F.R. § 1.144, applicants petition the Group Director to review the restriction requirement set forth in the Office Action mailed on September 24, 2002, maintained in the Office Actions mailed December 3, 2002, and maintained and clarified on September 2, 2003. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-1868.

The September 24, 2002 Restriction Requirement

The Office Action mailed September 24, 2002, divided the 23 claims into 9 groups:

Group I, claims 1, 2, and 6-9, drawn to a method for making a tissue engineering

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scaffold for inducing formation of extracellular matrix by cells bound to the scaffold comprising coupling matrix-enhancing molecules to the scaffold wherein the matrix enhancing molecule is TGF-β (Class 623, subclass 11).

Group II, claims 1-3 and 6-8, drawn to a method for making a tissue engineering scaffold for inducing formation of extracellular matrix by cells bound to the scaffold comprising coupling matrix-enhancing molecules to the scaffold wherein the matrix enhancing molecule is angiotensin II (Class 623, subclass 11).

Group III, claims 1, 2, 4, and 6-8, drawn to a method for making a tissue engineering scaffold for inducing formation of extracellular matrix by cells bound to the scaffold comprising coupling matrix-enhancing molecules to the scaffold wherein the matrix enhancing molecule is insulin-like growth factor (Class 623, subclass 11).

Group IV, claims 1,2, and 5-8, drawn to a method for making a tissue engineering scaffold for inducing formation of extracellular matrix by cells bound to the scaffold comprising coupling matrix-enhancing molecules to the scaffold wherein the matrix enhancing molecule is ascorbic acid (Class 623, subclass 11).

Group V, claims 10-15, drawn to a tissue engineering scaffold for inducing formation of extracellular matrix by cells bound to the scaffold comprising coupled to the scaffold matrix-enhancing molecules in an effective density to elicit production of extracellular matrix without increasing cellular proliferation wherein the matrix enhancing molecule is TGF-β (Class 530, subclasses 355 and 350).

Group VI, claims 16, 17, and 21-23, drawn to a method for repair or

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replacement of tissue comprising applying or implanting a tissue engineering scaffold comprising coupled to the scaffold matrix-enhancing molecules in an effective density to elicit production of extracellular matrix without increasing cellular proliferation wherein the matrix-enhancing molecule is TGF-β (Class 424, subclass 422).

Group VII, claims 16, 18, and 21-23, drawn to a method for repair or replacement of tissue comprising applying or implanting at a site in need of repair a tissue engineering scaffold comprising coupled to the scaffold matrix-enhancing molecules in an effective density to elicit production of extracellular matrix without increasing cellular proliferation wherein the matrix-enhancing molecule is TGFβ (Class 424, subclass 423).

Group VIII, claims 16, 19, and 21-23, drawn to a method for repair or replacement of tissue comprising applying or implanting at a site in need of repair a tissue engineering scaffold comprising coupled to the scaffold matrix-enhancing molecules in an effective density to elicit production of extracellular matrix without increasing cellular proliferation wherein the matrix-enhancing molecule is insulin-like growth factor (Class 424, subclass 423).

Group IX, claims 16, 20, and 21-23, drawn to a method for repair or replacement of tissue comprising applying or implanting at a site in need of repair a tissue engineering scaffold comprising coupled to the scaffold matrix-enhancing molecules in an effective density to elicit production of extracellular matrix without increasing cellular proliferation wherein the matrix-enhancing molecule is ascorbic

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acid. (Class 424, subclass 423).

In the response filed October 17, 2002, Applicants elected for prosecution Group I, claims 1, 2 and 6-9 with traverse. Furthermore, asserting that the restriction was improper, the proper action being an election of species, Applicants elected TGF-β as the species for the prosecution of the claims.

The Examiner maintained the restriction requirement in the Office Action dated December 3, 2002, despite Applicants arguments. The Examiner indicated that claims 3-5 and 10-23 were withdrawn from consideration. In the response to Office Action, Applicants canceled claims 10-23 but argued that claims 3-5 should be rejoined with Group I. In the Office Action dated September 2, 2003, the Examiner refused to rejoin claims 3-5. An appendix sets forth pending claims 1-9. The claims have not been amended during prosecution.

The Claims

Claims 1-9 are drawn to a method for making a tissue engineering scaffold containing a matrix-enhancing molecule for inducing formation of extracellular matrix. The claims are structured in a genus-species relationship as defined by MPEP 806.04.

It is well established that a generic claim cannot be restricted into groups. The examiner therefore clearly erred when he placed claims 1-9 into four separate groups.

Claims 1, 2 and 6 are generic. There is no limitation in these claims specific to particular matrix-enhancing molecules. Generic claim 1 is directed to a method of making a tissue engineering scaffold containing a matrix-enhancing molecule. This

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clearly encompasses the scope of dependent claims 3-5, which further define the matrix-enhancing molecule as being angiotensin II (claim 3), insulin-like growth factor (claim 4), and ascorbic acid (claim 5). These compounds are all related as being enhancers of extracellular matrix ***and all fall within the scope of independent claim 1.***

The proper action in this application is to require an election of species between TGFβ, angiotensin II, insulin-like growth factor and ascorbic acid. On October 17, 2002, in the response to restriction requirement, Applicants elected TGF-β.

The Legal Standard

Claims must be both patentably distinct and independent in order to be subject to restriction requirement. Definitions are provided by CHISUM 4:12.03[1]: The Patent and Trademark Office defines "independent" as meaning "not dependent," which in turn means "there is no disclosed relationship between the two or more subjects disclosed." Examples include species not usable together as disclosed or process and apparatus incapable of being used in practicing the process. The Office cites the extreme example of a shoe and a locomotive bearing. The Office defines "distinct" as meaning related or dependent but "capable of separate manufacture, use or sale as claimed" and "patentable over each other." Examples of dependent and distinct inventions include combination and subcombination, process and apparatus, process and product, and composition and process of use under appropriate circumstances.

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In an election of species, only the elected species is initially examined. Once this claim is deemed to be allowable, the examiner must search the remaining species.

Further, the MPEP states that species, "while usually independent, may be related under the particular disclosure. Where inventions as disclosed and claimed are both (A) species under a claimed genus and (B) related, then the question of restriction must be determined by both the practice applicable to election of species and the practice applicable to other types of restrictions such as those covered in MPEP 806.05-806.05(i)." (MPEP 806.04(b))

The MPEP provides that if an applicant discloses multiple species but includes only generic claims, election between species is normally not required. If an applicant discloses multiple species and includes claims restricted to those species, the applicant will be required to elect one species. He will then be restricted to those claims that read on that elected species unless a generic claim is found to be allowable. In the latter event, the applicant may include further claims to additional species (up to a reasonable number) provided that such additional claims "are written in dependent form (Rule 75), or otherwise include all the limitations of the generic claim."

The restriction requirement, by creating separate inventions out of the generic claims, makes it impossible to examine the claims in their entirety, and deprives applicants of claimed subject matter without an appealable examination.

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The examiner has no legal authority to require applicants to restrict a generic claim to a single species, absent prior art or lack of enablement.

Summary

The current restriction imposed on the claims of the present invention is improper. This restriction is inconsistent with the guidelines for restriction practice delineated by the MPEP. Upholding this restriction requirement would be to allow the examiner to impose limitations on the claims ***which are not now present.***

Favorable consideration of this petition is earnestly solicited.

Respectfully submitted,

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Certificate of Facsimile Transmission

I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted to the Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Peggy Bailey

Date: February 3, 2004

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Appendix: Claims As Pending

1. A method for making a tissue engineering scaffold for inducing formation of extracellular matrix by cells bound to the scaffold comprising coupling matrix-enhancing molecules to the scaffold in an effective density to elicit production of extracellular matrix without increasing cellular proliferation, wherein when the matrix-enhancing molecules are TGF-β, the TGF-β is coupled to the matrix by a polymer tether having a molecular weight between 2000 and 6000 and is in a density between 1 and 100 ng TGF-β/ml or in a concentration of between about 4×10^{-6} and 4×10^{-3} nmol/mL.

2. The method of claim 1 further comprising attaching cells to the scaffold.

3. The method of claim 1 wherein the matrix-enhancing molecules are angiotensin II.

4. The method of claim 1 wherein the matrix-enhancing molecules are insulin-like growth factor.

5. The method of claim 1 wherein the matrix-enhancing molecules are ascorbic acid.

6. The method of claim 1 wherein the matrix-enhancing molecules are covalently coupled to tethers which are covalently coupled to the scaffold.

7. The method of claim 1 wherein the scaffold is a hydrogel.

8. The method of claim 7 wherein the hydrogel is formed of a polymer selected from the group consisting of alginate, collagen, hyaluronic acid, and polyethylene glycol polymers.

9. The method of claim 7 wherein the matrix-enhancing molecules are TGF-β coupled to the hydrogel in a concentration of between about 4×10^{-6} and 4×10^{-3} nmol/mL.

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